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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/728,376 | 12/04/2003 | Jevan Damadian | 23242-1024 | 6384 |
| 7590 | 02/07/2005 | | EXAMINER | |
| Brandon N. Sklar, Esq. Kaye Scholer LLP 425 Park Avenue New York, NY 10022-3598 | | | LEE, KEVIN L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3753 | |

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------|------------------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/728,376 | DAMADIAN ET AL. <i>[Signature]</i> | |
| | Examiner KEVIN L LEE | Art Unit 3753 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on November 12, 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 13-22, 26-29 and 32-35 is/are rejected.
- 7) Claim(s) 23-25, 30 and 31 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>November 12, 2004</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 1-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 12, 2004.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18 and 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 18, the recitation that the "needle support is supported by the needle support" is vague and indefinite. In claim 26, "the needle support" lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13, 15, 17, 19-22, 26 and 33-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Kaplan et al (U.S. Patent No. 6,402,701). The patent to Kaplan et al discloses a method of conducting a needle biopsy procedure comprising reciprocating a biopsy needle (122) along its longitudinal axis, advancing the needle to a site of interest, collecting tissue at the site of interest and withdrawing the needle; see col. 13, lines 38-50 and col. 14, line 55 thru col. 15, line 10. The reciprocal motion of the needle (122) is accomplished via a motor (130), a coupling (214), a needle support (216) and a ball bearing (218), col. 13, lines 10-28.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan et al in view of Burney et al (U.S. Patent No. 5,800,389). The biopsy needle instrument of Kaplan et al lacks having a stylet. The patent to Burney et al teaches the above exception in providing a stylet (70) for a reciprocating biopsy needle (11), the stylet is received within a bore of the needle and serves to provide stiffness to the needle, therein guiding the needle through the lateral opening in the patient. The stylet is removed prior to taking the biopsy tissue sample, col. 7, lines 54-65 and col. 8, lines 36-42. In view of the teaching of Burney et al, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the instrument of Kaplan et al to include a removable stylet for the biopsy needle to provide stiffness to the needle, therein helping guide the needle to the site of interest in the patient. In particular regard to claim 16, Burney et al teaches reciprocating the needle while collecting the tissue so that the needle edge can help excise the tissue, col. 8, lines 52-55. In view of the teaching of Burney et al, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the operation procedure of Kaplan et al to include reciprocating the biopsy needle while collecting the tissue so that the needle edge can help excise the tissue.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan et al in view of Tsekos (U.S. Patent No. 6,675,037). Kaplan et al lacks teaching guiding the needle to the site of interest by MRI. The patent to Tsekos teaches the above exception in using MRI to guide a biopsy needle to a particular site of interest, col. 12,

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lines 33-55. In view of the teaching of Tsekos, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the operation procedure of Kaplan et al to include using MRI to guide the biopsy needle to the site of interest to more accurately locate the site biopsy site of interest.

Allowable Subject Matter

Claims 23-25, 30 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 27-29 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The patent to Kuhle (U.S. Patent No. 5,938,635) is cited for the additional teaching using MRI to guide a biopsy procedure. The patent to Evans (U.S. Patent No. 5,916,229) is cited for the showing of a solenoid and magnet drive for a biopsy needle.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN L LEE whose telephone number is (571) 272-4915. The examiner can normally be reached on MONDAY-THURSDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GENE MANCENE can be reached on (571) 272-4930. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 2, 2005


Kevin Lee
Primary Examiner